UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE-OPELOUSAS DIVISION

PAUL BREAUX	CIVIL ACTION NO.
VERSUS	JUDGE: _____
GLOBUS MEDICAL, INC AND GLOBUS MEDICAL NORTH AMERICA, INC.	MAGISTRATE
	JURY TRIAL REQUESTED

COMPLAINT FOR DAMAGES

NOW INTO COURT, through undersigned counsel, comes PAUL BREAUX (hereinafter referred to as "BREAUX"), a competent major domiciled in the Parish of Vermilion, State of Louisiana who respectfully asserts the following in support of his complaint for damages:

I. PARTIES

Made defendants herein are:

A. Globus Medical, Inc. and Globus Medical North America, Inc. (hereinafter referred to as "GLOBUS"), foreign corporations, whose principal business office is located in Audubon Pennsylvania who are authorized to do and doing business in the State of Louisiana with their principal business establishment in the State of Louisiana located in Baton Rouge, Louisiana.

SUBJECT MATTER JURISDICTION

2.

The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs and is between citizens of different States. The plaintiff is a citizen of the State of Louisiana and the defendants, "GLOBUS" are citizens of the State of Pennsylvania. Thus this Honorable Court has original jurisdiction pursuant to 28 U.S.C.A. § 1332.

PERSONAL JURISDICTION

3.

This Honorable Court has personal jurisdiction over GLOBUS as the event that is the subject of this lawsuit arises from one or more of the acts or activities listed in La. R.S. 13:3201, performed directly or by an agent, servant or employee of GLOBUS, including, but not limited to:

1) Transacting business in the State of Louisiana;

2) Contracting to supply services or things in the Parish of Lafayette, State of Louisiana;

3) Causing injury or damage by an offense or quasi offense committed through an act or omission in the Parish of Lafayette, State of Louisiana;

4) Causing injury or damage in the Parish of Lafayette, State of Louisiana by an offense or quasi offense committed through an act or omission outside of the State of Louisiana by GLOBUS who regularly does and/or solicits business, or engages in any other persistent course of conduct, or derives revenue from goods used or consumed or services rendered in the Parish of Lafayette, State of Louisiana;

5) Manufacturing the product described hereinafter or components thereof, which caused damage or injury in the Parish of Lafayette, State of Louisiana and, at the time of placing the product into the stream of commerce, GLOBUS, could have foreseen, realized, expected, or anticipated that the product may eventually be found in the Parish of Lafayette, State of Louisiana by reason of its nature and the marketing practices of GLOBUS.

VENUE

4.

Pursuant to 28 U.S.C. § 1391, venue is proper in the United States District Court, Western District of Louisiana, Lafayette-Opelousas Division in that :

1) GLOBUS contracted to supply services or things in the Parish of Lafayette, State of Louisiana;

2) The injury caused to the plaintiff was by an offense or quasi offense committed through an act or omission in the Parish of Lafayette, State of Louisiana;

3 The injury or damage caused by GLOBUS occurred in the Parish of Lafayette, State of Louisiana by an offense or quasi offense committed through an act or omission outside of the State of Louisiana by GLOBUS who regularly does and/ or solicits business, or engages in any other persistent course of conduct, or derives revenue from goods used or consumed or services rendered in the Parish of Lafayette, State of Louisiana;

4) GLOBUS manufactured the product described hereinafter or components thereof, which caused damage or injury in the Parish of Lafayette, State of Louisiana and, at the time of placing the product into the stream of commerce, GLOBUS, could have foreseen, realized, expected, or anticipated that the product may eventually be found in the Parish of Lafayette, State of Louisiana by reason of its nature and the marketing practices of GLOBUS.

FACTS

5.

On or about July 8,2015 BREAUX underwent an anterior cervical diskectomy at C5-6, C6-7 which included a Medtronic cadaveric bone graft at C5-6,C6-7; Medtronic Atlantic Elite plate C5 through C7; an anterior cervical diskectomy and replacement at C7-T1 which involved the insertion and placement of a Globus Medical SECURE-C Artificial Disc replacement at C7-T1.

6.

The surgery and insertion and placement of the aforementioned Globus Medical SECURE-C Artificial Disc replacement at C7-T1 was performed by William A. Brennan, M.D. at Regional Medical Center of Acadiana, 2810 Ambassador Caffery Parkway, Lafayette, Louisiana 70506.

7.

William A. Brennan, M.D. described the operative procedure in detail as follows:

"The patient was taken to the operating room, placed in supine position, and general

endotracheal anesthesia was administered. After adequate anesthesia was achieved, the patient's arms were tucked to the side and the right side of the neck was shaved, prepped and draped in sterile fashion, making a transverse incision with a #15 scalpel blade directly over the superior portion of the clavicle, I exposed the platysma layer. The monopolar insulated pinpoint cautery was used to incise this layer and identified the medial border of the sternocleidomastoid muscle. This medial border was dissected and the space between the tracheoesophageal complex and the carotid sheath was separated using Metzenbaum scissors and blunt dissection. The esophageal retractor was used with Kitner dissectors to identify the disk space. Needle localization with C-arm fluoroscopy identified at C6-7. It was decided to do the cervical disk replacement first so as not to increase the chance of hardware collision later on. The C7-T1 interspace was identified. The longus colli muscles were coagulated bilaterally and a Black Belt retractor installed. The distracting pins for C7 and T1 were installed and distraction applied. The annulus of the disk was incised with a #15 scalpel blade. Multidirectional pituitary rongeurs and curettes were used to evacuate the disk space. Posterior longitudinal ligament was opened with 1 and 2 mm Kerrison rongeurs and a rectangular dissection was extended out past the uncinate process into the cervical nerve root foramen. The patency of the cervical nerve root foramen was confirmed with a nerve hook. The endplates were cleaned of all disk material and the 6mm trial was installed. The cutting keels placed after C-arm fluoroscopic guidance of the trial. The keels were then trialed, were then removed and the 6-mm 6-degree implant was chosen. This was tapped into position and position found with 3D fluroscope to be satisfactory. Attention was then turned to the upper levels.

The C5-6 are was identified and the longus colli muscle was used to coagulate and a Black Belt retractor was installed. Distracting pins were placed in C5 and C6 distraction applied. The

annulus of the disk was incised with a #15 scalpel blade and multidirectional pituitary rongeurs and curettes were used to evacuate the disk space. The patient had a rectangular dissection with 1 and 2 mm Kerrison rongeurs through the posterior longitudinal ligament exposing the dura and the cervical nerve root foramen which were all decompressed and checked with a nerve hook. The endplates were decorticated with the Midas Rex drill and the direct vision with a bone trap and a mallet after being hydrated with saline. The patient then had distraction pins removed and the dissection taken down to C6-7 where an identical procedure was performed.

After all three levels had been treated, the C5 to C7 area was treated with an Atlantis Medtronic titanium cervical locking plate. A 45mm plate was slightly dense to fit and installed with 15 mm variable angle screws. The screws were then locked to the plate. X-ray confirmed placement and the wound was copiously irrigated with antibiotic saline and closed after hemostasis with 2-0 Vicryl pop-off suture in the platysmal layer and the skin closed at the skin layer with 4-0 Prolene subcuticular. Sterile dressing was applied. All counts were correct. The patient was reversed from general endotracheal anesthesia, awoke, moving all 4 extremities and taken to recovery room in stable condition.

8.

BREAUX was released from the hospital the following day, July 9, 2016 wiithout any notation of complication byWilliam Brennan, M.D.

9.

On or about August 10, 2015, BREAUX began to experience new intermittent burning and shocking pain in his neck and right forearm pain and numbness.

10.

On or about August 11, 2015, a cervical MRI was performed on BREAUX that revealed that the Globus Medical SECURE-C Artificial Disc replacement at C7-T1 had failed to perform and/or function as designed causing the artificial disc to extrude and/or migrate from its original location in construction resulting in a right lateral disc extrusion/herniation at C7-T1 resulting in moderate to severe proximal right foraminal stenosis.

11.

BREAUX was required to undergo an additional surgery, namely an Anterior Cervical Diskectomy Fusion which included the removal of the Globus Medical SECURE-C Artificial Disc replacement at C7-T1 and replacement with a C7-T1 fusion with Medtronic graft and C5-T1 plate.

12.

At all times pertinent hereto, GLOBUS acted individually and/or through its agents, servants or employees, as specified below, for which GLOBUS is independently and vicariously liable.

13.

At all times pertinent hereto, GLOBUS is in the business of manufacturing the Globus Medical SECURE-C Artificial Disc replacement for placement into trade or commerce in Louisiana.

14.

At all times pertinent hereto, GLOBUS produced, made, fabricated, constructed, and designed the, Globus Medical SECURE-C Artificial Disc replacement for placement into trade or commerce in Louisiana.

15.

A all times pertinent hereto, GLOBUS labeled as its own the Globus Medical SECURE-C

Artificial Disc replacement for placement into trade or commerce in Louisiana.

16.

At all times pertinent hereto, GLOBUS sold the Globus Medical SECURE-C Artificial Disc replacement in Louisiana and exercised control over or influenced characteristics of the design, construction or quality of the Globus Medical SECURE-C Artificial Disc replacement.

17.

GLOBUS is a manufacturer under the Louisiana Products Liability Act (9:2800.51, et seq.) and Redhibition (La.C.C. Art. 2520, et seq).

Unreasonably Dangerous Characteristics

18.

At all times pertinent hereto, within the meaning and scope of La. R. S. 9:2800.55-9:2800.59, the Globus Medical SECURE-C Artificial Disc replacement possessed unreasonably dangerous characteristics that were a proximate cause of injury and damage to BREAUX.

19.

GLOBUS is liable unto BREAUX for the damages proximately caused by the characteristics of the Globus Medical SECURE-C Artificial Disc replacement that rendered it unreasonable dangerous, namely for the product to remain secure and intact once implanted, when said damage arose from a reasonably anticipated use of the SECURE-C Artificial Disc replacement by BREAUX.

Unreasonably Dangerous
In Construction or Composition

20.

BREAUX incorporates by reference of the allegations contained in 12-19, above as if copied in extenso.

21.

When the Globus Medical SECURE-C Artificial Disc replacement left the control of GLOBUS, the product was unreasonably dangerous in construction, composition, and materials as specified below.

22.

Alternatively, when the Globus Medical SECURE-C Artificial Disc replacement left the control of GLOBUS, the product deviated in a material way from the specifications or performance standards of GLOBUS or from otherwise identical products manufactured by GLOBUS.

23.

The Globus Medical SECURE-C Artificial Disc replacement is constructed or composed of two SECURE-C Endplates and one SECURE-C core.

24.

The Globus Medical SECURE-C Artificial Disc replacement's SECURE-C Core is designed to have an engagement feature on the inferior surface of the SECURE-C Core to secure the SECURE-C core between the SECURE-C Endplates.

25.

As constructed or composed, the SECURE-C Core in the SECURE-C Artificial Disc replacement implanted in BREAUX failed to stay secure and/or in position between the SECURE-C Endplates as designed.

26.

The failure of the SECURE-C core in the SECURE-C Artificial Disc replacement implanted in BREAUX failed because of the construction and/or composition of the engagement feature on

the inferior surface of the SECURE-C Core and/or because of the construction and/or composition of the SECURE-C Endplates.

Unreasonably Dangerous In Design

27.

Alternatively, when the product left the control of GLOBUS the SECURE-C Artificial Disc replacement was unreasonably dangerous in design as specified below.

28.

Petitioners incorporate by reference all of the allegations contained in 12-27, above as if copied in extenso.

29.

As designed, if the engagement feature on the SECURE-C Core is not present and/or fails to perform as designed the SECURE-C core can extrude from the SECURE-C endplates resulting in a disc extrusion/herniation resulting in foraminal stenosis and/or injury to the spine and/or requiring the person implanted with the device to undergo additional surgery.

30.

As designed, the SECURE-C Core is susceptible to failure, namely that it is not secure and susceptible to extrude from the SECURE-C Endplates resulting in possible injury to the spine thus rendering it unreasonably dangerous.

31.

Alternatively, as designed, if the SECURE-C Core was secure at the time implanted into BREAUX then the SECURE-C Endplates are ineffective, and thus unreasonably dangerous as they allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and

impinge upon the spine and/or spinal nerves resulting in injury to the spine.

32.

As designed, it is foreseeable that a person implanted with the SECURE-C Artificial Disc replacement would stand, sit, lay, run, climb, jog, walk, lift, bend and fall.

33.

As designed, it is foreseeable that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

34.

At the time the SECURE-C Artificial Disc left the control of GLOBUS an alternative design for an artificial disc existed that was capable of preventing the damage caused to BREAUX.

35.

Moreover, as designed, the likelihood that the SECURE-C Artificial Disc would cause damage to BREAUX and the gravity of the damage done to BREAUX outweighed the burden on GLOBUS of adopting the alternative design and outweighed the adverse effect of the alternative design on the utility of the SECURE-C Artificial Disc.

36.

When the SECURE-C Artificial Disc left the control of GLOBUS, GLOBUS knew and, because of scientific and technological information available at the time, should have known that, as designed, the SECURE-C Artificial Disc was unreasonably dangerous and an alternate design was feasible.

Inadequate Warnings

37.

Petitioners incorporate by reference of the allegations contained in 6-36, above as if copied in extenso.

38.

Alternatively, the SECURE-C Artificial Disc was unreasonably dangerous, because its warnings were not adequate, specifically there was no warning that the petitioner could experience the product failure and damages that he incurred.

39.

When the SECURE-C Artificial Disc left their control, GLOBUS knew or should have known that the SECURE-C Artificial Disc possessed characteristics that could cause damage to BREAUX and GLOBUS failed to use reasonable care to provide an adequate warning of such characteristics.

40.

GLOBUS knew or should have known that an ordinary user with knowledge common to the community would not realize the danger created by the unreasonably dangerous composition, construction, materials or design of the SECURE-C Artificial Disc.

41.

GLOBUS knew or should have known that the unreasonably dangerous composition, construction, materials or design of the SECURE-C Artificial Disc are not obvious to an ordinary consumer.

42.

GLOBUS failed to warn consumers or users of the SECURE-C Artificial Disc that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

43.

GLOBUS has no warnings that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

Not Conforming To Express Warranty

44.

Petitioners incorporate by reference of the allegations contained in 6-43, above as if copied in extenso.

45.

The SECURE-C Artificial Disc was unreasonably dangerous because it violated its express warranty.

46.

The SECURE-C Artificial Disc is marketed as a motion-sparing technology designed as an alternative to fusion. GLOBUS markets and advertises the SECURE-C Artificial Disc "Through its unique selectively constrained design, SECURE-C is designed to allow up to ± 15° motion in flexion-extension and up to ±10° motion in lateral bending. The design is intended to allow

unlimited axial rotation and to permit sagittal plane translation of ±1.25mm. Clinical study data demonstrates statistical superiority of SECURE-C® ACDF in terms of overall success, subsequent surgery and patient satisfaction at 24 months postoperative.

47.

GLOBUS SECURE-C Artificial Disc is guaranteed against faulty materials and workmanship, including engineering, composition, construction and design. In fact GLOBUS advertises and markets their products, including the SECURE-C Artificial Disc with "Life Moves Us" stating that "This passion, combined with Globus' world class engineering, transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible.

48.

GLOBUS breached these warranties for the reasons set forth 6-47, above, which are incorporated by reference as if copied in extenso, which were a cause of the accident, injury, and damage to BREAUX.

Redhibition
(La.C.C. Art. 2520, et seq.)

49.

Petitioners incorporate by reference of the allegations contained in 6-48, above as if copied in extenso.

50.

At all times pertinent herein, GLOBUS is the manufacturer of the SECURE-C Artificial Disc that was implanted into BREAUX.

51.

The SECURE-C Artificial Disc that was implanted into BREAUX possessed a redhibitory defect as defined by La.C.C.Art. 2520. Namely, the SECURE-C Artificial Disc's SECURE-CORE extruded and/or migrated from the SECURE ENDPLATES that was implanted into BREAUX causing the core to impinge upon his spine and/or spinal nerves resulting in injury to his spine and requiring him to undergo additional surgery to remove the device which resulted in him suffering extensive permanent injury and damages.

52.

The defects in the SECURE-C Artificial Disc that was implanted into BREAUX were not known to BREAUX at the time of sale and could not have been discovered by a reasonable prudent buyer of such things.

53.

GLOBUS is the manufacturer of the SECURE-C Artificial Disc that was implanted into BREAUX and thus BREAUX is not required to give GLOBUS notice of the existence of a redhibitory defect in the SECURE-C Artificial Disc.

54.

BREAUX returned the defective SECURE-C Artificial Disc that was implanted into him to GLOBUS.

55.

For those reasons stated herein, the SECURE-C Artificial Disc that was implanted into BREAUX was useless or so inconvenient that BREAUX would not have bought the SECURE-C Artificial Disc had he known of the defect. The existence of the defect described herein gives

BREAUX the right to obtain recission of the sale and all damages that flow therefrom, including but not limited to return of the price with interest from the time it was paid, for the reimbursement of the reasonable expenses occasioned by the sale to include those expenses incurred to implant the device, to remove the device and to repair any and all damage caused therefrom, along with reasonable attorney fees.

Negligence
La. C.C. Arts. 2315, 2316, 2317, 2317.1, 2320, 2322, and 2324

56.

In the alternative, Petitioners incorporate by reference all of the allegations contained in 6-55, above as if copied in extenso.

57.

Alternatively, GLOBUS, individually and through its agents, servants, and employees, provided professional services that resulted in the design, construction, composition, marketing, and selling of the SECURE-C Artificial Disc.

58.

Alternatively, within the meaning and scope of La. C.C. Arts. 2315, 2316, 2317, 2317.1, 2320, 2322, and 2324, the accident, injury, and damage to BREAUX was caused by the fault of GLOBUS individually and/or its and/or their agents, servants or employees which consisted of, but is not limited to, the following:

1. Failure to educate and/or inform and/or warn their sales representatives as to SECURE-C Artificial Disc qualities, propensity, limitations and risks;

2. Failure to educate and/or inform and/or warn the physicians and/or hospitals that purchased the SECURE-C Artificial Disc of its qualities, propensity, limitations and risks;

3. Failure to educate and/or inform and/or warn the end user of the SECURE-C Artificial Disc of its qualities, propensity, limitations and risks;

4. Failure to educate and/or inform and/or warn their sales representatives that there is a risk or danger that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

5. Failure to educate and/or inform and/or warn the physicians and/or hospitals who would implant the SECURE-C Artificial Disc that there is a risk or danger that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

6. Failure to educate and/or inform and/or warn the end user that there is a risk or danger that every day movement and/or minimal trauma could allow for the SECURE-C Core to extrude and/or migrate from within the SECURE-C Endplates and impinge upon the spine and/or spinal nerves resulting in injury to the spine and requiring the person implanted with the device to undergo additional surgery to remove the device.

7. Distributing a defective device;

8. Distributing a device that is unreasonable dangerous in construction, composition, design, lacks adequate warning and fails to conform to express warranty;

9. Other acts of negligence that may discovered.

Damages

59.

Because of the failure of the SECURE-C Artificial Disc, BREAUX suffered injuries and damages, as hereinafter stated, for which each is entitled in an amount reasonable in the premises.

60.

Because of the breach of duty owed by the defendants to the plaintiff as set forth herein, namely the defects and failure of the SECURE-C Artificial Disc, BREAUX has sustained damages, consisting of past, present and future mental and physical pain and suffering, loss of earnings and earning capacity, disability, the loss of enjoyment of life, past and future medical expenses for which he is entitled to an amount reasonable in these premises, in addition to any punitive or treble damages allowed by any applicable law and/or choice of law that are reasonable from the premises set forth herein, along with the return of the price with interest from the time it was paid, for the reimbursement of the reasonable expenses occasioned by the sale to include those expenses incurred to implant the device, to remove the device and to repair any and all damage caused therefrom, along with reasonable attorney fees. costs and attorney fees.

Prayer

WHEREFORE, the plaintiff, PAUL BREAUX prays that the defendants, Globus Medical, Inc. and Globus Medical North America, Inc. be duly cited and served and that after a lapse of all legal delays and proceedings that there be a judgment in favor of Paul Breaux and against the defendants, Globus Medical, Inc. and Globus Medical North America, Inc. severally, jointly and in solido, for all damages, general, special and exemplary, for which this Honorable Court finds reasonable, together with legal interest thereon from date of judicial demand until paid, for all costs of these proceedings and for other general, equitable and specific relief, to which plaintiffs are entitled.

Respectfully submitted by:

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